

REMARKS/ARGUMENTS

The Applicants believe that, in view of the arguments presented below, the pending claims are in condition for allowance. The Applicants therefore respectfully request reconsideration and withdrawal of the rejection issued on January 27, 2006.

35 U.S.C. § 112 – New Matter

The Examiner rejected all of the pending claims under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for containing new matter not described in the specification. Contrary to the Examiner's rejection, the recitation "without any aid from any structures additional to the microchannels" is not new matter and is supported in the written description. This recitation is clearly set out in the specification when the term "spontaneous fluid transport" is used and defined. Moreover, this recitation agrees with the understanding of the term "spontaneous fluid transport" that was pointed out by the Examiner in an earlier office action. *See Office Action, November 12, 2005, at 3.* Applicants have only amended the claims to better clarify "spontaneous fluid transport" as already recited in the claims in such a way as complies with the written description of the specification.

"The inquiry into whether the description requirement is met is a question that must be determined on a case-by-case basis and is a question of fact." Manual of Patent Examining Procedure § 2363.04. The "inquiry is primarily factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure." *Id.* at § 2163 II.A. The specification may support the language of the claims "through express, implicit, or inherent disclosure." *Id.* at § 2163 I.B. "An objective standard for determining compliance with the written description requirements is, does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." [quotations omitted] *Id.* at § 2163.02 "[T]he fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." *Id.* at § 2163.02.

The recitation "without any aid from any structures additional to the microchannels" directly follows from the description of "spontaneous fluid transport" as put forth in the specification and as would be interpreted by one of skill in the art. One of skill in the art would see that the specification teaches fluid flow due to the microchannels made from the fluid control film. Fluid control film is defined as a "film or sheet or layer having at least one major surface

AN 09/612,418
Page 8

comprising a microreplicated pattern capable of manipulating, guiding, containing, spontaneously wicking; transporting, or controlling, a fluid." Specification, page 10, lines 22-24. The fluid transport nature of the microstructured fluid control film layers used to form the detection articles of the present invention allows for the easy introduction of fluid sample into the structure through capillary action, without the need for additional processes such as sample input by syringe or pipetting." *Id.* at page 6, lines 9-12.

The specification further states that the "acquisition zones of the present invention are capable of wicking a fluid sample into the detection article unaided." Specification, page 26, lines 13-14 [emphasis added]. "[O]nly fluid contact between the acquisition zone 210 and a liquid sample is necessary" to transport the liquid throughout the detection article. *Id.* at page 29, lines 5-6. "The acquisition zone preferably includes two or more channels that are capable of wicking a fluid sample into the article by spontaneous liquid transport." *Id.* at page 4, lines 23-25. The channels are described as being capable of moving the fluid sample and moving the fluid sample spontaneously. Furthermore, "channels 204 provide a means to wick or transport a liquid sample into the acquisition zone 210, between the acquisition zone 210 and the detection zone 220, and into the detection zone 220, by spontaneous and uniform fluid transport, or capillary action, throughout the length of the channels 204." *Id.* at page 24, lines 17-21.

As stated by the Examiner, this recitation excludes "ANY additional material within the channel which contribute[s] to fluid flow." Final Office Action, January 27, 2006, page 3. The interpretation may exclude a wick or other structure that is placed in or on the microchannel. However, contrary to the Examiner's assertion, this interpretation does not exclude the material forming the surface of the microchannel. A polymer or other material incorporated into the surface of the microchannel (and thus forming the microchannel), however, such as those materials described on page 20 line 25 through page 21 line 2, are part of the surface of the microchannel and are therefore not "additional structure."

The Examiner also opined that claims 4, 40, and 44-45 contain additional structures within the channels. Final Office Action, page 4. These additional structures are "detection elements" that may be present at certain points in the microchannels. These detection elements, however, do not provide any aid to the transport of fluids in the detection article. Moreover, any alternative embodiments that may include some additional structure that aids in transport of the

AN 09/612,418
Page 9

fluid throughout the microchannels are not being claimed, but are only put forth in the specification as unclaimed examples.

In addition, the thread recited and discussed by the Examiner on page 4 of the Final Office Action on January 27, 2006 is not causing any fluid transport. Rather the "minute piece of thread 430 placed with [sic] a groove of one or more of the channels 404" instead "provides support that presents a probe for target capture." Specification, page 43, lines 14-15. As further discussed page 49, the target may be an enzyme or a molecule that is to be collected from the fluid flowing through the microchannels. The thread does not, however, aid or need to aid the spontaneous fluid transport caused by the microchannels.

It is the microchannels themselves, without any additional aid, whether external or internal, that causes the spontaneous fluid transport of the present invention. Contrary to the Examiner's position, this feature is set forth in the specification such that one of skill in the art to recognize what the Applicants are claiming and is therefore not new matter.

Claim 1 Is Not Obvious In View Of Tso

Claims 1-3, 5-9, 41, 46, 60-61, and 83-85 were rejected under 35 U.S.C. 103(a) as obvious in view of U.S. Patent No. 6,613,560 to Jacqueline Tso et al. ("Tso"). One or more sections of Tso relied upon by the Examiner, however, are not prior art to the present application. The information relied upon was not included until the continuation-in-part application that resulted in the '560 Patent was filed on February 11, 2000.

The enclosed 37 U.S.C. § 1.131 declaration is from the first named inventor of the present application, Raymond P. Johnston. As noted in the declaration, the inventors were in possession of "the conception to provide spontaneous fluid transport through a microchannel in a detection article" before February 10, 2000. Furthermore, microchannels such as shown on page 7 of the record of invention (included with the declaration) were made before February 10, 2000. These detection articles provide the spontaneous fluid flow as claimed in the present application. The "spontaneous fluid displacement" information included in Tso, and relied upon by the Examiner, did not appear in the parent application to Tso and so does not benefit from the dates of the earlier filed applications. Because at the Applicants were in possession of the conception claimed in the present application before the filing of the Tso application that is relied on by the Examiner, the Tso application is not prior art.

AN 09/612,418
Page 10

The Examiner's reliance on Tso to reject the claims based upon the "spontaneous fluid displacement" recited in Tso is obviated and the Applicants therefore respectfully request that the rejection based upon Tso be reconsidered and withdrawn.

CONCLUSION

All of the claims remaining in this application should now be seen to be in condition for allowance. The prompt issuance of a notice to that effect is respectfully solicited. If there are any remaining questions, the Examiner is requested to contact the undersigned at the number listed below.

No fee is believed to be necessary for the entry of this paper. Should any fee be required for entry of this paper, the Commissioner is authorized to charge the Faegre & Benson Deposit Account No. 06-0029 and in such event, is requested to notify us of the same.

Respectfully Submitted,

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